



Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS

ACTION: Notice

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N39, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Organ Procurement and Transplantation Network and Scientific Registry of Transplant Recipients Data System OMB No. 0915-0157– Revision.

Abstract: Section 372 of the Public Health Service (PHS) Act, as amended, requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). This is a request for revisions to current OPTN data collection forms associated with an individual's clinical characteristics at the time of registration, transplant, and follow-up after the transplant. These specific data elements of the OPTN data system are collected from transplant hospitals. The information is used to indicate the disease severity of transplant candidates, to monitor compliance of member organizations with OPTN rules and requirements, to report periodically on the clinical and scientific status of organ donation and transplantation and other purposes consistent with the law. Data are used to:

- (1) facilitate organ placement and match donor organs with recipients;
- (2) monitor compliance of member organizations with federal laws and regulations and with OPTN requirements;
- (3)

review and report periodically to the public on the status of organ donation and transplantation in the United States; (4) provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation; and (5) perform transplantation-related public health surveillance including possible transmission of donor disease. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of Health and Human Services, and members of the public for evaluation, research, patient information, and other important purposes.

Likely Respondents: Transplant programs, medical and scientific organizations, and public organizations.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to: (1) review instructions; develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; (2) train personnel to respond to a request for collection of information; (3) search data sources; (4) complete and review the collection of information; and (5) to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Section/Activity	Number of Respondents	Average Number of Responses per Respondent	Total Number of Responses	Average Burden per Response (in hours)	Total Burden Hours
Deceased Donor Registration	58	158.2	9175.6	1.1	10093.2
Living Donor Registration	307	20.6	6324.2	1.8	11383.6
Living Donor Follow-up	307	60.7	18634.9	1.3	24225.4
Donor Histocompatibility	154	96.7	14891.8	0.2	2978.4
Recipient Histocompatibility	154	173.5	26719	0.4	10687.6
Heart Candidate Registration	132	30.5	4026	0.9	3623.4
Heart Recipient Registration	132	19.9	2626.8	1.2	3152.2
Heart Follow Up (6 Month)	132	17	2244	0.4	897.6
Heart Follow Up (1-5 Year)	132	73.9	9754.8	0.9	8779.3
Heart Follow Up (Post 5 Year)	132	115.2	15206.4	0.5	7603.2
Heart Post-Transplant Malignancy Form	132	11	1452	0.9	1306.8
Lung Candidate Registration	70	39.6	2772	0.9	2494.8
Lung Recipient Registration	70	28.3	1981	1.2	2377.2
Lung Follow Up (6 Month)	70	26.2	1834	0.5	917.0
Lung Follow Up (1-5 Year)	70	99.4	6958	1.1	7653.8
Lung Follow Up (Post 5 Year)	70	65.6	4592	0.6	2755.2
Lung Post-Transplant Malignancy Form	70	1.5	105	0.4	42.0
Heart/Lung Candidate Registration	69	0.7	48.3	1.1	53.1
Heart/Lung Recipient Registration	69	0.4	27.6	1.3	35.9
Heart/Lung Follow Up (6 Month)	69	0.3	20.7	0.8	16.6
Heart/Lung Follow Up (1-5 Year)	69	1.5	103.5	1.1	113.9
Heart/Lung Follow Up (Post 5 Year)	69	3.1	213.9	0.6	128.3
Heart/Lung Post-Transplant Malignancy Form	69	0.2	13.8	0.4	5.5
Liver Candidate Registration	141	89.2	12577.2	0.8	10061.8
Liver Recipient Registration	141	48.8	6880.8	1.2	8257.0
Liver Follow-up (6 Month - 5 Year)	141	231.1	32585.1	1	32585.1
Liver Follow-up (Post 5 Year)	141	256.5	36166.5	0.5	18083.3
Liver Recipient Explant Pathology Form	141	12.3	1734.3	0.6	1040.6
Liver Post-Transplant Malignancy	141	13.2	1861.2	0.8	1489.0
Intestine Candidate Registration	40	4.4	176	1.3	228.8
Intestine Recipient Registration	40	3.4	136	1.8	244.8

Section/Activity	Number of Respondents	Average Number of Responses per Respondent	Total Number of Responses	Average Burden per Response (in hours)	Total Burden Hours
Intestine Follow Up (6 Month - 5 Year)	40	13.3	532	1.5	798.0
Intestine Follow Up (Post 5 Year)	40	13.5	540	0.4	216.0
Intestine Post-Transplant Malignancy Form	40	0.6	24	1	24.0
Kidney Candidate Registration	238	162.6	38698.8	0.8	30959.0
Kidney Recipient Registration	238	71.8	17088.4	1.2	20506.1
Kidney Follow-Up (6 Month - 5 Year)	238	379.5	90321	0.9	81288.9
Kidney Follow-up (Post 5 Year)	238	346.7	82514.6	0.5	41257.3
Kidney Post-Transplant Malignancy Form	238	18.1	4307.8	0.8	3446.2
Pancreas Candidate Registration	141	3.4	479.4	0.6	287.6
Pancreas Recipient Registration	141	1.8	253.8	1.2	304.6
Pancreas Follow-up (6 Month - 5 Year)	141	8.2	1156.2	0.5	578.1
Pancreas Follow-up (Post 5 Year)	141	13.5	1903.5	0.5	951.8
Pancreas Post-Transplant Malignancy Form	141	0.8	112.8	0.6	67.7
Kidney/Pancreas Candidate Registration	141	9.6	1353.6	0.6	812.2
Kidney/Pancreas Recipient Registration	141	5.2	733.2	1.2	879.8
Kidney/Pancreas Follow-up (6 Month - 5 Year)	141	26.9	3792.9	0.5	1896.5
Kidney/Pancreas Follow-up (Post 5 Year)	141	48.2	6796.2	0.6	4077.7
Kidney/Pancreas Post-Transplant Malignancy Form	141	1.6	225.6	0.4	90.2
VCA Candidate Registration	23	1.7	39.1	0.4	15.6
VCA Recipient Registration	23	1.7	39.1	1.3	50.8
VCA Recipient Follow Up	23	1.7	39.1	1	39.1
Total	457*		471411.4		359889.5

*Total number of OPTN transplant hospitals as of October 23, 2015. Number of respondents for transplant candidate or recipient forms is based on number of organ specific programs associated with each form.

****Bold** entries represent those forms being modified during this submission.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated:

Jackie Painter

Director, Division of the Executive Secretariat

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